PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Paul M. Scopton	Confirmation No.:	8323
Serial No.:	09/498,104	Examiner:	M. DeSanto
Filing Date:	February 4, 2000	Group Art Unit:	3763
Docket No.:	1001.1375101	Customer No.:	28075

For: FLUID INJECTABLE SINGLE OPERATOR EXCHANGE CATHETERS AND METHODS OF USE

Mail Stop Appeal Brief - Patents
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APPEAL BRIEF UNDER 37 C.F.R. § 1.192

CERTIFICATE UNDER 37 C.F.R. 1.10: The undersigned hereby certified that this paper or papers, as described herein are being deposited in the United States Postal Service, "Express Mail Post Office to Addressee" having an Express Mail mailing label number of: EV 315614082 US, in an envelope addressed to: Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 24th day of May 2004.

By Kathleen L Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 1.192, Appellant hereby submits this Appeal Brief in triplicate in furtherance of the Notice of Appeal filed on March 23, 2004. Enclosed herewith is a check in the amount of $165.00 to cover the fee prescribed by 37 C.F.R. § 1.17(c). Permission is hereby granted to charge or credit deposit account number 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, Minnesota 55311. An assignment from the inventor Paul Scopton conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 010587, Frame 0187.

II. RELATED APPEALS AND INTERFERENCES

Neither Appellant, Appellant's legal representatives, nor assignee know of any other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-5 and 7 stand finally rejected under 35 U.S.C. §102(e) as being anticipated by Sirhan (U.S. Patent No. 5,984,945). Claims 1-5, 7, 10-13, and 15 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Crittenden et al. (U.S. Patent No. 4,988,356). Claims 1-5, 7-9, 10-13, and 15-17 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Horzewski et al. (U.S. Patent No. 4,771,777). Claims 18-20 are being canceled in an amendment After Final filed herewith. Appellant hereby appeals the final rejection of all pending claims 1-5, 7-13, and 15-17.

IV. STATUS OF AMENDMENTS

An After Final response and request for reconsideration was mailed on January 22, 2004 in response to the Final Office Action mailed November 24, 2003. No amendments were made. An Advisory Action was mailed on February 20, 2004, in which the rejections of claims 1-5, 7-9, 10-13, and 15-17 under 35 U.S.C. §§ 102(e) and 102(b) were sustained. In the Advisory Action, the Examiner indicated that the Amendment After Final mailed on January 22, 2004 overcame the rejection of claims 1-5, 7, 10-13, and 15 over Ressemann et al. (U.S. Patent No. 5,281,203). An Amendment After Final in which previously withdrawn claims 18-20 are canceled is being filed concurrently with this brief.

V. SUMMARY OF INVENTION[1]

The invention relates to a single operator exchange biliary catheter (please see, for example, specification at page 4, lines 3-13) having an injection lumen extending through a shaft, and a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, with the guidewire lumen in fluid communication with the injection lumen (please see, for example, specification at page 6, lines 4-8). The biliary catheter also has a tubular member connected to the shaft that defines a guidewire lumen extension that is external to and parallel to the shaft and is axially aligned with the guidewire lumen (please see, for example, specification at page 6, lines 8-21). The guidewire lumen extension is in fluid communication with the guidewire lumen (please see, for example, specification at page 11, lines 1-3). The inclusion of the tubular member forming an external, parallel, axially aligned guidewire lumen extension allows for retraction of the guidewire from the guidewire lumen to minimize flow resistance from the guidewire during fluid injection, while maintaining guidewire lumen access for re-insertion of the guidewire.

VI. ISSUES

1. Whether claims 1-5 and 7 are anticipated under 35 U.S.C. §102(e) by Sirhan (U.S. Patent No. 5,984,945).

2. Whether claims 1-5, 7, 10-13, and 15 are anticipated under 35 U.S.C. §102(b) by Crittenden et al. (U.S. Patent No. 4,988,356).

3. Whether claims 1-5, 7-9, 10-13, and 15-17 are anticipated under 35 U.S.C. §102(b) by Horzewski et al. (U.S. Patent No. 4,771,777).

VII. GROUPING OF CLAIMS

Claims 1-5 and 7 are rejected as a group under a first grounds of rejection, claims 1-5, 7, 10-13 and 15 are rejected under the second grounds of rejection, and claims 1-5, 7-13 and 15-17 are rejected as a group under the third grounds of rejection. Appellant asserts that all claims do not stand or fall together, but rather claims 1-5, and 7-9 stand or fall together as a group, and claims 10-13 and 15-17 stand or fall together as a group. Pursuant to 37 C.F.R. § 1.192(c)(7),

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[1] The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

reasons why all of the claims do not stand or fall together are presented in the Argument section below.

VIII. ARGUMENT

A. Claims 1-5 and 7 are patentable over Sirhan (U.S. Patent No. 5,984,945).

Independent claim 1 recites a single operator exchange biliary catheter having an elongate shaft with an injection lumen extending through the length and a guidewire lumen extending through a distal portion. The catheter also includes a tubular member connected to the shaft forming a guidewire lumen extension. The claim specifically recites the guidewire lumen extension is external to and parallel to the shaft, and is axially aligned with the guidewire lumen. Sirhan fails to teach a device with these features. The anticipation rejection is thus improper.

The device of Sirhan is an exchange device for replacing guidewires during angioplasty, and is thus quite different from the claimed single operator exchange biliary catheter. On pages 2-3 of the Final Office Action mailed November 24, 2003, the Examiner asserts that figures 6-10 and 15 and the entire Sirhan reference teaches the limitations of independent claim 1. The Examiner does not, however, state which parts of the Sirhan device are being interpreted to anticipate the various parts of the claimed invention. On page 6 of the After Final response mailed January 22, 2004, Appellant made various assumptions regarding which parts of the Sirhan device were being equated with specific parts of the claimed invention and asked the Examiner to clarify the rejection if the assumptions were incorrect. In the Advisory Action mailed February 20, 2004, the Examiner again only referred to Figures 6 and 15 of Sirhan in general, and did not clarify which features of the Sirhan device were being equated with the specifically recited features of the claims. Because the Examiner has not indicated any errors in the previous assumptions made by Appellant, the following arguments are based on those assumptions.

Looking at figures 6-10 of Sirhan, Appellant assumes the catheter 27 of Sirhan is being equated with the *elongate shaft* of instant claim 1, the inner lumen 30 of Sirhan with the *guidewire lumen* of instant claim 1, the tubular section 11,12 of Sirhan with the *tubular member* of instant claim 1, and the lumen 15 of Sirhan with the *guidewire lumen extension* of instant claim 1. In the device of Sirhan, the tubular member 11,12 enters the catheter 27 at an angle, as shown in figures 6-10 and 15. The external portion of the tubular member of Sirhan is not

axially aligned with the shaft, but rather is on a converging axis. Therefore, the lumen 15 of Sirhan is not parallel with the catheter 27 and is not axially aligned with the inner lumen 30 of the catheter 27. The embodiment shown in figure 15 of Sirhan includes a portion of the distal tubular section 12 that is parallel with the shaft, but this portion is inside the shaft. Sirhan thus does not teach or contemplate a catheter in which a tubular guidewire lumen extension is located external to and parallel to the main shaft, and is axially aligned with the shaft, as is recited in independent claim 1.

Claims 3, 4, and 5 recite the tubular member being disposed about the shaft (claim 3), having a distal end fluidly sealed about the shaft (claim 4), and being sized to restrict flow about the guidewire disposed therein (claim 5). Thus the device of claims 3-5 not only has a tubular member external and parallel to the shaft, but also has the tubular member disposed around the shaft. The tubular section 11,12 of Sirhan is not disposed about the shaft, or catheter 27. Instead, in the device of Sirhan, the tubular section 11,12 is inserted into the catheter 27, as shown in figures 8-10. In fact, Sirhan specifically teaches away from this feature. Sirhan expressly states that the distal tip 17 of the exchange device is beveled or tapered to facilitate entry into the catheter. See column 4, lines 42-45. In describing the operation of his device, Sirhan states that the "distal tip of the exchange device is seated within the proximal guidewire port 29." See column 5, lines 47-48. Sirhan thus fails to teach the limitations of claims 3 and 4. Sirhan also fails to teach a proximal portion of a guidewire lumen extension being sized to restrict flow about the guidewire disposed therein, as is required in claim 5.

Claim 7 states that the shaft of the biliary catheter is radially shifted at the proximal guidewire port so the guidewire remains straight, as shown in Fig. 3. The catheter of Sirhan does not shift radially at the proximal guidewire port. In figures 6-10 and 15 of Sirhan, the catheter shaft 27 at the proximal guidewire port 29 clearly remains linear and is not radially shifted. The Examiner asserts that figures 6 and 15 of Sirhan show radial shifting, but does not point out any particular parts or regions of the device of Sirhan which are radially shifted. As instant claim 7 recites the shaft of the catheter as being radially shifted at the proximal guidewire port, Sirhan would have to show his catheter shaft 27 being radially shifted at the proximal guidewire port 29 in order to anticipate the claims. The figures of Sirhan fail to show such feature. Additionally, Sirhan does not teach or contemplate such a feature in the description of the invention. Sirhan

thus does not teach each and every limitation of the instant claims, as is required for anticipation under 35 U.S.C. §102. Withdrawal of the rejection is respectfully requested.

B. Claims 1-5, 7, 10-13, and 15 are patentable over Crittenden et al. (U.S. Patent No. 4,988,356).

Independent claims 1 and 10 recite a catheter shaft having a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port. Crittenden et al. fail to teach these features. Crittenden et al. teach a guidewire exchange system in which a catheter is slit longitudinally along its length to receive a bare guidewire inserted through a guide member. The device of Crittenden et al. includes a guiding device that "serves to merge or to separate the guidewire and catheter lumen at any location along the length of the guidewire or catheter." See column 2, lines 38-42. The device of Crittenden et al. does not have guidewire ports, and in fact, no ports are needed because the longitudinal slit allows the guidewire to be inserted at any point along the catheter. In the Advisory Action mailed February 20, 2004, the Examiner states that he is interpreting "ports" as any opening, "thus wherever the tubular member ends, the opening distal that point is the proximal guidewire port." Appellant respectfully disagrees.

MPEP 2111 states that claims must be given their broadest reasonable interpretation, and quotes *In re Morris*, 44 USPQ2d 1023, 1027-1028 (Fed. Cir. 1997), where the court held that "the PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification." MPEP 2111 also cites *In re Cortright*, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) for the holding that the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. Appellant submits that the broadest reasonable interpretation of "port" consistent with how one of ordinary skill in the art would interpret the word does not include "slit." The term "port" is used in the catheter art to indicate a discrete opening at a single location on the catheter shaft.

For example, the Sirhan patent cited by the Examiner clearly distinguishes between discrete guidewire ports 14, 29 in figures 1, 2, and 7-10, and the lengthwise slits 20, 22 in the hypotubing 18 and jacket 19 in figures 1 and 3. See column 4, lines 38-41, and 51-54, and column 5, lines 10-14 of Sirhan (U.S. Patent No. 5,984,945). Moore et al. (U.S. Patent No.

5,531,700), previously cited by the Examiner, provides another example of one or ordinary skill in the art using the term "port" to indicate a discrete opening in a catheter shaft. Moore et al. teach a catheter having a distal guide wire exit port 24 and a proximal guide wire exit port 30. See column 7, lines 38-39 and 50 and figure 2. McInnes (U.S. Patent No. 6,322,577), also previously cited by the Examiner, provides further evidence that one of ordinary skill in the art would recognize a distinction between a guidewire "port" and a "slit" in a catheter. McInnes teaches a catheter with a proximal guidewire port 17 and perfusion ports 21, 22, described at column 5, lines 24-26 and shown in figure 1. These are clearly discrete openings in the catheter. McInnes also teaches a slit 31 that extends from the proximal guidewire port 17 to a location proximal to the proximal perfusion port 21. See column 5, lines 53-55. Thus, McInnes demonstrates that one of ordinary skill in the art of catheters distinguishes between discrete "ports" and "slits" that extend along the length of a catheter, often between ports.

The interpretation of the term "port" as not including "slit" is further supported by the fact that Crittenden et al. refer to the longitudinal opening (reference number 28) in their device as a "slit" and do not use the term "port." Based on the use of the terms "port" and "slit" in the catheter art, Appellant submits that one of ordinary skill in the art would not interpret the slit 28 in the Crittenden et al. device as a "port" as is recited in the instant claims. The Examiner's interpretation of the claim language is contrary to that of the ordinary artisan. Crittenden et al. thus fail to teach each and every limitation of independent claims 1 and 10 and, therefore, also fail to teach the limitations of the claims dependent thereon. Withdrawal of the rejection is respectfully requested.

C. Claims 1-5, 7-9, 10-13, and 15-17 are patentable over Horzewski et al. (U.S. Patent No. 4,771,777).

Independent claim 1 recites a catheter shaft having an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, and a tubular member extending proximally from the proximal guidewire port defining a guidewire lumen extension in fluid communication with the guidewire lumen. Horzewski et al. fail to teach these features.

Horzewski et al. teach a perfusion balloon dilation system with a catheter having an inflation lumen 36, a guidewire/flow lumen 46, and a removable slit sheath 71. See column 3, lines 3-8; column 4, lines 8-10; column 5, lines 1-6; and figures 1-4. Horzewski et al. teach the

slit sheath 71 as extending along the catheter such that it is in close proximity to a first balloon to locate or position the guidewire 66 adjacent the shaft. See column 5, lines 15-20. As shown in figure 1, and in greater detail in figure 4, the slit sheath 71 is adjacent to, but is not connected to the proximal guidewire port 47 of the guidewire/flow lumen 46.

On page 6 of the Final Office Action mailed November 24, 2003, the Examiner asserted that the tubular member 71 of Horzewski et al. extends proximally from the proximal guidewire port, has a distal end fluidly sealed about the shaft, and a proximal portion sized to restrict flow about the guidewire disposed therein. Horzewski et al. simply do not teach these limitations. As is clearly shown in figure 4, the sheath (tubular member) 71 does not extend from guidewire port 47, but is actually spaced apart from port 47. The purpose for sheath 71 described by Horzewski et al. is that it "locates or positions the guide wire 66 adjacent the shaft of the balloon dilation catheter formed by the tubular member 31." See column 5, lines 15-20. Because the sheath 71 of Horzewski et al. functions to position the guidewire, there is no reason for it to extend from or otherwise be connected to the guidewire port.

Independent claim 1 also recites the guidewire lumen extension as being in fluid communication with the guidewire lumen. The Examiner did not address this limitation of claim 1 in the anticipation rejection under Horzewski et al. in the Final Office Action mailed November 24, 2003. In the Advisory Action mailed February 20, 2004, the Examiner asserted that "fluid would be capable of being transferred from the tubular member to the shaft since that is what is claimed." It appears the Examiner may have misinterpreted the claim language in the reference. Horzewski et al. refer to the catheter shaft in the claims as a "tubular member." However, in the Final Office Action mailed November 24, 2003, the Examiner equated the instantly claimed "tubular member" with reference number 71 of Horzewski et al., which is the slit sheath. While the catheter shaft of Horzewski et al. is described as being sealed and providing fluid flow, the slit sheath 71 is not.

Claims 4 and 5 recite the tubular member fluidly sealed about the shaft and sized to restrict flow about the guidewire disposed therein, respectively. Horzewski et al. do not teach or contemplate these limitations. Horzewski et al. teach the function of the sheath as positioning the guidewire close to the shaft, not for having fluid flowing through it. Thus there is no reason for the sheath to be fluidly sealed about the shaft or to restrict fluid flow. Claim 7 recites the shaft of the catheter radially shifted at the proximal guidewire port. Horzewski et al. fail to teach

this limitation. As shown in figure 1, the shaft 31 of the catheter remains linear throughout its length. Additionally, Horzewski et al. provide no teaching or suggestion of a radial shift to the catheter shaft.

Independent claim 10 recites a catheter shaft having an injection lumen and an inflation lumen extending therethrough, a guidewire lumen extending through a distal portion, and a tubular member defining a guidewire lumen extension in fluid communication with the guidewire lumen. Horzewski et al. fail to teach these limitations. The catheter shaft of Horzewski et al. has only two lumens; the first inflation/deflation lumen 36, and the second guidewire/flow lumen 46. See column 3, lines 3-8; column 4, lines 8-10; and figures 3 and 4. Claim 10 also recites a tubular member disposed about the shaft forming a guidewire lumen extension that is in fluid communication with the guidewire lumen. As stated above, Horzewski et al. merely teach a sheath 71 surrounding the shaft adjacent to the guidewire port, but not in fluid communication with the port. There is no teaching or suggestion in Horzewski et al. of having the sheath 71 provide a fluid flow path communicating with the guidewire lumen 46 in the catheter.

Claims 12, 13 and 15 recite the tubular member fluidly sealed about the shaft, being sized to restrict flow about the guidewire, and the shaft being radially shifted at the proximal guidewire port, respectively. As stated above, Horzewski et al. fail to teach or contemplate these limitations. Withdrawal of the rejection is respectfully requested.

D. Separate Patentability of Claim Groupings

As noted above, Appellant submits that claims 1-5 and 7-9 stand or fall together, and claims 10-13 and 15-17 stand or fall together. Independent claim 1 and the claims dependent thereon are separately patentable from independent claim 10 and the claims dependent thereon. The separate patentability of independent claims 1 and 10 is evidenced by the fact that, while the three references used in the rejections are all asserted to anticipate the claims, the Sirhan reference is applied to independent claim 1 but not independent claim 10. This indicates that claims 1 and 10 are separately patentable.

While independent claims 1 and 10 are subject to the same rejections over the Crittenden et al. and Horzewski et al. references, the claims are separately patentable based on their separate features and limitations. Independent claim 1 recites a tubular member extending proximally from the proximal guidewire port. This limitation is not found in independent claim 10, and is

not found in either Crittenden et al. or Horzewski et al., as stated above. Independent claim 10 recites a catheter shaft having an inflation lumen and balloon, and a tubular member disposed about the shaft. These limitations are not found in independent claim 1. Neither Crittenden et al. nor Horzewski et al. teach these limitations. As indicated above, the Crittenden et al. and Horzewski et al. references fail to teach many of the features of the claims. Therefore, the mere fact that the Examiner has included both independent claims 1 and 10 in the rejections under these references does not support an assertion that the claims should stand or fall together.

IX. CONCLUSION

For the reasons stated above, the rejection of claims 1-5, 7-13, and 15-17 under 35 U.S.C. §§ 102(b) and 102(e) should be reversed.

Respectfully submitted,

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By his attorney,

Date: 5/24/04

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X. APPENDIX OF CLAIMS

1. A single operator exchange biliary catheter for use in combination with a guidewire and an endoscope, comprising:

an elongate shaft having a proximal end, a distal end and an injection lumen extending therethrough;

a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft within the distal portion of the shaft, the distal guidewire port disposed at the distal end of the shaft;

a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension in fluid communication with the guidewire lumen and adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein, the guidewire lumen extension being external to but parallel with the shaft; and

wherein the guidewire lumen extension is axially aligned with the guidewire lumen.

2. A biliary catheter as in claim 1, wherein the tubular member has a distal end disposed distal of the proximal guidewire port.

3. A biliary catheter as in claim 2, wherein the tubular member is disposed about the shaft.

4. A biliary catheter as in claim 3, wherein the distal end of the tubular member is fluidly sealed about the shaft.

5. A biliary catheter as in claim 4, wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein.

6. (cancelled)

7. A biliary catheter as in claim 1, wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port.

8. A biliary catheter as in claim 1, wherein the tubular member has a length of approximately 5 to 30 cm.

9. A biliary catheter as in claim 8, wherein the tubular member comprises a heat shrink tube.

10. A single operator exchange biliary balloon catheter for use in combination with a guidewire and an endoscope, comprising:

an elongate shaft having a proximal end, a distal end, an injection lumen and an inflation lumen extending therethrough;

an inflatable balloon disposed adjacent the distal end of the shaft in fluid communication with the inflation lumen;

a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft within the distal portion of the shaft, the distal guidewire port disposed at the distal end of the shaft; and

a tubular member disposed about the shaft, the tubular member having a proximal end disposed distal of the proximal end of the shaft, and a distal end disposed distal of the proximal guidewire port, the tubular member defining a guidewire lumen extension in fluid communication with the guidewire lumen and adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein, the guidewire extension lumen being external to but parallel with the shaft;

wherein the guidewire lumen extension is axially aligned with the guidewire lumen.

11. A single operator exchange biliary balloon catheter as in claim 10, wherein the distal end of the tubular member is disposed adjacent the proximal guidewire port.

12. A single operator exchange biliary balloon catheter as in claim 11, wherein the distal end of the tubular member is fluidly sealed about the shaft.

13. A single operator exchange biliary balloon catheter as in claim 12, wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein.

14. (cancelled)

15. A single operator exchange biliary balloon catheter as in claim 10, wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port.

16. A single operator exchange biliary balloon catheter as in claim 10, wherein the tubular member has a length of approximately 5 to 30 cm.

17. A single operator exchange biliary balloon catheter as in claim 16, wherein the tubular member comprises a heat shrink tube.

18-20. (cancelled)